

AMENDMENTS TO THE SPECIFICATION

Please replace the paragraph at page 31, lines 10-24 with the following amended paragraph:

A further aspect of the present invention is a sanitization assembly for the *in situ* sanitization during start-up and shutdown of the fluid processor. See, FIGS. 10A to 11B. For simplicity, the process control system is not shown in FIGS. 10A, 10B and 11B. The sanitization assembly comprises an isolation valve 184, a drain valve 190 (see, FIG. 11A and B), and a start-up loop (see, FIGS. 10A and 10B) comprised of a start-up loop flow restrictor 160 and a four-way valve 162 having a startup position and a normal position. Referring to FIG. 10A and 10B, the isolation valve ~~[[168]]~~ 184 is located downstream of a fluid source 166 and upstream of the pump 170 and allows for isolating the system from the fluid source 166. The drain valve 190 (see, FIG. 11A and 11B) is located upstream of the processor assembly 181 and at the lowest point of the fluid processor. The drain valve allows for draining fluid from the system. The startup flow restrictor 160 (see, FIGS. 10A and 10B) controls the flow rate through the startup loop. The startup flow restrictor 160 is located immediately downstream of the isolation valve ~~[[168]]~~ 184 along a first fluid path that is separate from but running parallel to a second fluid path going from the isolation valve ~~[[168]]~~ 184 to the pump 170. The four way valve 162 is disposed downstream of the flow restrictor 160 and the pump 170.

Please replace the paragraph at page 32, lines 9-21 with the following replacement paragraph:

For sanitization during startup, a fluid inlet 164 is connected to the fluid source 166 which has a minimum line pressure of not less than about 10 psia and not greater than about

800 psia (e.g. a tap water line). The four-way valve 162 is then switched to its start-up position and the isolation valve ~~[[168]]~~ 184 is opened. Instead of activating the pump 170, the fluid is driven by line pressure to enter the reactor 172 at a small flow rate that is regulated by the start-up loop flow restrictor 160. A heater 176 is switched on and, as the reactor 172 heats up, steam is generated for sterilizing the system. This steam goes through the tube side of the heat exchanger 174 and flows downstream of the processor assembly to exits at a fluid outlet 178. After steam has gone through the fluid outlet 178 for a period of time sufficient to sterilize the system, the four-way valve 162 is switched to its normal position (see, FIG. 10B). The pump 170 is then turned on and the fluid processor is allowed to stabilize at the desired temperature and pressure for period of time before product is collected from the fluid outlet 178.

Please replace the paragraph running from page 32, line 22 to page 33, line 16 with the following replacement paragraph.

The sterilization procedure during shutdown is as follows. See FIGS. 11A and 11B. The pump 180 and heater 182 are turned off. The isolation valve 184 from the fluid source 186 to the system is turned off. As the fluid in the fluid processor components that are downstream of the reactor 186 is expelled through the fluid outlet 188 by the pressure of the steam generated by the residual heat of the reactor 186, the drain valve 190 is opened to discharge fluid in the fluid processor components that are upstream of the processor assembly 181 (see, arrow S). After the fluid ceases to flow from the fluid outlet 188, a bag 194 (or, alternatively, a syringe) containing a sufficient amount of sterile solution is connected to fluid outlet 188, and the drain valve 190 is closed. See, FIG. 11B. For simplicity, the components of the process control system ~~[[200]]~~ 210 and treatment assembly ~~[[210]]~~ 200 of FIG. 11A

are not shown in FIG. 11B. Examples of suitable sterile solutions are a greater than about 50% aqueous solution of isopropyl alcohol or a dilute hydrogen peroxide solution. As the system cools down and the steam within the fluid processor condenses, a partial vacuum is created which causes the sterile solution in the bag 194 to be drawn into the fluid processor to fill up the internal volume of the system. The bag 194 is left on the fluid output 188 while the fluid processor is stored away until the next use. Referring to FIG. 11B, an alternative approach (shown in dotted line) is to use a filter 194 (e.g., a HEPA filter) to end cap the fluid output 188. The filter allows air to pass through and functions as a barrier to prevent any airborne contaminants from getting into the system.